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09/388,090 08/31/99 JACKSON

W 7969-082

EXAMINER

HM12/0517

PENNIE & EDMONDS LLP
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

DEVI, S

ART UNIT

PAPER NUMBER

1645

13

DATE MAILED:

05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/388,090

Applicant(s)
Jackson et al.

Examiner
S. Devi, Ph.D.

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/28/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-39 and 48-53 ~~is~~/are pending in the application.
- 4a) Of the above, claim(s) 53 ~~is~~/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 49 ~~is~~/are allowed.
- 6) ☒ Claim(s) 37, 39, 48, and 50-52 ~~is~~/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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Art Unit: 1645

DETAILED ACTION

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 02/28/01 (paper no. 12) in response to the Office Action mailed 12/11/2000 (paper no. 11).

Status of Claims

- 2) Claims 1-36 and 40-47 have been canceled via the amendment filed 09/25/99.
Claims 37-39 have been amended via the amendment filed 09/25/99.
New claims 48-53 have been added. Claims 37-39 and 48-53 are pending.
Claim 53 is withdrawn from consideration as being directed to a non-elected invention.
Claims 37-39 and 48-52 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

- 5) The objection to the drawings made in paragraph 7 of the Office Action mailed 12/11/2000 (paper no. 11) in connection with the problems noted by the Draftsperson is maintained for reasons set forth therein.

Objection(s) Moot

- 6) The objection to claims 40 and 41 made in paragraph 14 of the Office Action mailed 12/11/2000 (paper no. 11) is moot in light of Applicants' cancellation of the claims.

Objection(s) Withdrawn

- 7) The objection to the specification made in paragraphs 8(b), 8(c) and 8(d) of the Office Action mailed 12/11/2000 (paper no. 11) is withdrawn in light of Applicants' amendments to the specification.

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8) The objection to claims 37-39 made in paragraph 14 of the Office Action mailed 12/11/2000 (paper no. 11) is withdrawn in light of Applicants' amendments to the claims.

Objection(s) Maintained

9) The objection to the specification made in paragraph 8(a) of the Office Action mailed 12/11/2000 (paper no. 11) is maintained. Although Applicants have amended certain parts of the specification to delete the hyperlink recitations, others remain uncorrected. For example, see page 11, line 9. It is suggested that Applicants examine the whole specification to make similar corrections to the hyperlinks, wherever hyperlinks appear.

Rejection(s) Moot

10) The rejection of claim 41 made in paragraph 10 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Lehninger AL (*Principles of Biochemistry*, Worth Publishers, Inc., New York, Chapter 27, pp. 793-836, 1982) is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 41 made in paragraph 11 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Cleton-Jensen *et al.* (*Mol. Gen. Genet.* 229: 2: 206-212, 1991) is moot in light of Applicants' cancellation of the claim.

12) The rejection of claim 41 made in paragraph 12 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Matsuhara *et al.* (WO 9514772) is moot in light of Applicants' cancellation of the claim.

13) The rejection of claims 40 and 41 made in paragraph 13 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(a) as being anticipated by Billing-Medel *et al.* (WO 9818945, 07 May 1998) is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

14) The rejection of claims 37 and 38 made in paragraph 10 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Lehninger AL (*Principles of Biochemistry*, Worth Publishers, Inc., New York, Chapter 27, pp. 793-836, 1982) is withdrawn in light of Applicants' amendments to the claims.

15) The rejection of claims 37 and 38 made in paragraph 11 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Cleton-Jensen *et al.* (*Mol. Gen. Genet.* 229: 2: 206-212, 1991) is withdrawn in light of Applicants' amendments to the claims.

16) The rejection of claims 37 and 38 made in paragraph 12 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(b) as being anticipated by Matsuhara *et al.* (WO 9514772) is withdrawn in light of Applicants' amendments to the claims.

17) The rejection of claims 38 and 39 made in paragraph 13 of the Office Action mailed 12/11/2000 (paper no. 11) under 35 U.S.C § 102(a) as being anticipated by Billing-Medel *et al.* (WO 9818945, 07 May 1998) is withdrawn in light of Applicants' amendments to the claims.

New Rejection(s)

Applicants are asked to note the new rejection(s) made in this Office Action. The Applicants's amendments, including the addition of new claims, necessitated the new ground(s) of rejection presented in this Office Action.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

18) Claims 37, 39 and 50-52 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claims 37 and 39 are vague and indefinite in the use of abbreviations in the claim language. It is suggested that each abbreviation be recited as a full terminology at first occurrence, with its abbreviated recitation retained in parentheses.

(b) Claim 50-52, which depend from claim 37 or 39, is also rejected under 35 U.S.C § 112, second paragraph, as being indefinite, because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

19) Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim currently includes the limitation of “/1 mM NaCl/” (see line 5 of the claim). However, there appears to be no descriptive support in the instant specification for this newly added limitation. The rest of the hybridization conditions have descriptive support on page 25, lines 5-9, wherein --0.25M NaCl-- is used, but not 1 mM NaCl. Applicants state that support for the amendments to the claim can be found in section 5.7. However, this part of the specification does not provide support for the limitation of “/1 mM NaCl/”.

The new limitation in the claim is therefore considered to be new matter. *In re Rasmussen*, 650 F.2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation, or to remove the new matter from the claim.

Rejection(s) under 35 U.S.C § 102

20) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

21) Claims 37 and 50-52 are rejected under 35 U.S.C § 102(e) as being anticipated by Gilbert *et al.* (US 6,096,529, filed 06/10/1996).

Gilbert *et al.* disclose an isolated polynucleotide sequence (i.e., DNA) encoding an isolated polypeptide of *Neisseria gonorrhoeae* (i.e., not *N. meningitidis*) having a molecular weight of about 40 kD as determined by SDS polyacrylamide gel electrophoresis, a recombinant expression cassette, an expression vector and a host cell comprising the same (see column 2, lines 6-20; Example 2; column 4, lines 10-26; column 8, lines 42-50; and column 15, second and third full paragraphs).

Although Gilbert *et al.* refer to their polypeptide as NGSP and are silent about the use of glutamic dehydrogenase, carbonic anhydrase and myoglobin-blue as molecular weight markers as recited in instant claims, the prior art DNA or the polynucleotide sequence is viewed as the same as the Applicants' claimed DNA, and the 40 kD polypeptide encoded by the prior art DNA is viewed as the same as the instantly recited 40 kD polypeptide. The Office's position that Gilbert's DNA or the polynucleotide sequence and the polypeptide encoded by the same are the same as the Applicants' DNA or the polynucleotide sequence and the polypeptide encoded by the same is based upon the fact that every characteristic overlapping in Gilbert's and Applicants' disclosure are the same. In spite of the fact that Gilbert *et al.* do not expressly teach the use of the three molecular weight markers recited in claim 37, since the prior art polynucleotide sequence and the polypeptide encoded by the same are structurally the same as the instantly claimed nucleotide sequence and the polypeptide encoded by the same, the polypeptide is expected inherently to show a molecular weight of 40 kD when glutamic dehydrogenase, carbonic anhydrase and myoglobin-blue are used as molecular weight markers in SDS gel electrophoresis. Absent evidence that the recited glutamic dehydrogenase, carbonic anhydrase and myoglobin-blue molecular weight markers change the structure of the encoded polypeptide or its molecular weight significantly, instant claims are anticipated by Gilbert *et al.*

Claims 37 and 50-52 are anticipated by Gilbert *et al.*

22) Claim 48 is rejected under 35 U.S.C § 102(b) as being anticipated by Zheng *et al.* (*Genetics* 143: 941-952, June 1996).

Zheng *et al.* teach an isolated nucleic acid comprising at least 21 contiguous nucleotides and showing 100% sequence homology with a fragment of the instantly recited SEQ ID NO: 3 (see the attached search report). That this nucleic acid encodes a polypeptide comprising at least seven amino acids, which constitute an antigenic epitope of the amino acid sequence of the polypeptide encoded by SEQ ID NO: 3 is inherent from the teachings of Zheng *et al.*

Claim 48 is anticipated by Zheng *et al.*

Remarks

23) Claims 37, 39, 48 and 50-52 stand rejected. Claims 38 and 49 are free of prior art and are allowed.

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24) THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

25) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.

26) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


S. Devi, Ph.D.
Patent Examiner
May 2001

Seq ID No. 3

Page 8

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RESULT 1
AG2H417/c 91 bp DNA INV 29-APR-1996
LOCUS AG2H417
DEFINITION A.gambiae satellite DNA (locus AG2H417).
ACCESSION 272082
VERSION 272082.1 GI:1292591
KEYWORDS satellite.
SOURCE African malaria mosquito.
ORGANISM Anopheles gambiae
          Eukaryota; Metazoa; Arthropoda; Tracheata; Hexapoda; Insecta;
          Pterygota; Diptera; Nematocera; Culicoidea; Culicidae; Anopheles.
REFERENCE 1 (bases 1 to 91)
AUTHORS Zheng, L., Benedict, M.O., Cornel, A.J., Collins, F.H. and Kafatos, F.C.
TITLE An integrated genetic map of the African human malaria vector
        mosquito, Anopheles gambiae
        Genetics 143 (1996) In press
JOURNAL 2 (bases 1 to 91)
REFERENCE Zheng, L.
AUTHORS Direct Submission
TITLE Submitted (23-APR-1996) Zheng L., European Molecular Biology
JOURNAL Laboratory, Meyerhofstrasse 1, 69117 Heidelberg, FRG
FEATURES Location/Qualifiers
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Best Local Similarity 100.0%; Pred. No. 0.21;
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Qy 1270 acccttcagacacataccgacag 1292
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Db 64 ACCCTTCAGACACATACCGACAG 42
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